K111039 (pg 1/2)

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

MAY 19 2011

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	April 13, 2011
Trade Name:	*Zimmer*® Periarticular Locking Plate System
Common Name:	Temporary Internal Fixation Devices
Classification Names and References:	Single/multiple component metallic bone fixation appliances and accessories - 21 CFR 888.3030, Smooth or threaded metallic bone fixation fastener - 21 CFR 888.3040
Predicate Devices:	*Zimmer* Periarticular Locking Plate System - K040593 (cleared 4/12/2004), K042598 (cleared 10/29/2004), K043227 (cleared 12/10/2004), K043560 (cleared 1/21/2005), K050121 (cleared 1/31/2005) and K051098 (cleared 7/7/2005)
Device Description:	The Zimmer Periarticular Locking Plate System is a plate and screw system. The low-profile periarticular plates are anatomically contoured with threaded holes to engage and "lock" the screws at a fixed angle relative to the plate.
Intended Use:	The Periarticular Locking Plate System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including: • Comminuted fractures, • Supracondylar fractures, • Intra-articular and extra-articular condylar fractures, • Fractures in osteopenic bone, • Nonunions, and • Malunions

Comparison to Predicate Device: Identical to the predicate devices – this submission is to add the sterile version of non-sterile devices

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Sterilization Validation** - To demonstrate that at a minimum gamma dose of 20kGy the devices can be terminally sterilized to a SAL greater than or equal to 10^{-6}.
- **Shelf Life** - Accelerated aging showed that the product has a shelf life of 10 years.
- **Sterile Packaging** - To withstand normal distribution and storage conditions and maintain the sterile barrier properties throughout the specified product shelf life.

Except for the sterilization status, sterile packaging and the addition of sterile text on the labels and in the package inserts, the sterile devices included in this submission are identical to their associated non-sterile predicate devices. The addition of sterile versions did not change the intended use or the fundamental scientific technology of any of the devices. Each sterile device uses the same operating principle and incorporates the same design and basic labeling.

In summary, the sterile devices described in this submission are substantially equivalent to their non-sterile counterparts.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 19 2011

Zimmer, Inc.
% Stephen H. McKelvey
Senior Project Manager
Trauma Regulatory Affairs
P.O. Box 708
Warsaw, IN 46581

Re: K111039
Trade/Device Name: *Zimmer*® Periarticular Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 13, 2011
Received: April 19, 2011

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): ~~K040593, K042598, K043227, K043560, K050121, K051098~~

Device Name:

Zimmer® Periarticular Locking Plate System

Indications for Use:

The Periarticular Locking Plate System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:

- Comminuted fractures,
- Supracondylar fractures,
- Intra-articular and extra-articular condylar fractures,
- Fractures in osteopenic bone,
- Nonunions, and
- Malunions

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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